

§ 414.330

42 CFR Ch. IV (10–1–10 Edition)

transplant surgeon after the 60-day period covered by the comprehensive payment, are made under the reasonable charge criteria set forth in § 405.502 (a) through (d) of this chapter. The payments for physicians' services in connection with renal transplantations are changed on the basis of program experience and the expected advances in the medical art for this operation.

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) *Equipment and supplies*—(1) *Basic rule.* Except as provided in paragraph (a)(2) of this section, Medicare pays for home dialysis equipment and supplies only under the prospective payment rates established at § 413.170.

(2) *Exception.* If the conditions in subparagraphs (a)(2) (i) through (iv) of this section are met, Medicare pays for home analysis equipment and supplies on a reasonable charge basis in accordance with subpart E (Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians) of part 405, but the amount of payment may not exceed the limit for equipment and supplies in paragraph (c)(2) of this section.

(i) The patient elects to obtain home dialysis equipment and supplies from a supplier that is not a Medicare approved dialysis facility.

(ii) The patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the "ESRD Beneficiary Selection" form).

(iii) In writing, the supplier—

(A) Agrees to receive Medicare payment for home dialysis supplies and equipment only on an assignment-related basis; and

(B) Certifies to CMS that it has a written agreement with one Medicare approved dialysis facility or, if the beneficiary is also entitled to military or veteran's benefits, one military or Veterans Administration hospital, for each patient. (See part 494 of this chapter for the requirements for a Medicare approved dialysis facility.) Under the agreement, the facility or military or VA hospital agrees to the following:

(1) To furnish all home dialysis support services for each patient in accordance with part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. (§ 410.52 sets forth the scope and conditions of Medicare Part B coverage of home dialysis services, supplies, and equipment.)

(2) To furnish institutional dialysis services and supplies. (§ 410.50 sets forth the scope and conditions for Medicare Part B coverage of institutional dialysis services and supplies.)

(3) To furnish dialysis-related emergency services.

(4) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are covered under the composite rate established at § 413.170 and to arrange for the laboratory to seek payment from the facility. The facility then includes these laboratory services in its claim for payment for home dialysis support services.

(5) To arrange for a Medicare approved laboratory to perform dialysis-related laboratory tests that are not covered under the composite rate established at § 413.170 and for which the laboratory files a Medicare claim directly.

(6) To furnish all other necessary dialysis services and supplies (that is, those which are not home dialysis equipment and supplies).

(7) To satisfy all documentation, recordkeeping and reporting requirements in part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with subpart U.

(iv) The facility with which the agreement is made must be located within a reasonable distance from the patient's home (that is, located so that the facility can actually furnish the needed services in a practical and timely manner, taking into account variables like the terrain, whether the patient's home is located in an urban or

rural area, the availability of transportation, and the usual distances traveled by patients in the area to obtain health care services).

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

(b) *Support services*—(1) *Basic rule*. Except as provided in paragraph (b)(2) of this section, Medicare pays for support services only under the prospective payment rates established in § 413.170 of this chapter.

(2) *Exceptions*. If the patient elects to obtain home dialysis equipment and supplies from a supplier that is not an approved ESRD facility, Medicare pays for support services, other than support services furnished by military or VA hospitals referred to in paragraph (a)(2)(iii)(B) of this section, under paragraphs (b)(2) (i) and (ii) of this section but in no case may the amount of payment exceed the limit for support services in paragraph (c)(1) of this section:

(i) For support services furnished by a hospital-based ESRD facility, Medicare pays on a reasonable cost basis in accordance with part 413 of this chapter.

(ii) For support services furnished by an independent ESRD facility, Medicare pays on the basis of reasonable charges that are related to costs and allowances that are reasonable when the services are furnished in an effective and economical manner.

(c) *Payment limits*—(1) *Support services*. The amount of payment for home dialysis support services is limited to the national average Medicare-allowed charge per patient per month for home dialysis support services, as determined by CMS, plus the median cost per treatment for all dialysis facilities for laboratory tests included under the composite rate, as determined by CMS, multiplied by the national average number of treatments per month.

(2) *Equipment and supplies*. Payment for home dialysis equipment and supplies is limited to an amount equal to the result obtained by subtracting the

support services payment limit in paragraph (c)(1) of this section from the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent) of the national median payment as determined by CMS that would have been made under the prospective payment rates established in § 413.170 of this chapter for hospital-based facilities.

(3) *Notification of changes to the payment limits*. Updated data are incorporated into the payment limits when the prospective payment rates established at § 413.170 of this chapter are updated, and changes are announced by notice in the FEDERAL REGISTER without a public comment period. Revisions of the methodology for determining the limits are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

[57 FR 54187, Nov. 17, 1992, as amended at 73 FR 20474, Apr. 15, 2008]

EFFECTIVE DATE NOTE: At 75 FR 49202, Aug. 12, 2010, § 414.330 was amended by removing “§ 413.170” and adding in its place “§ 413.210” in paragraph (a)(1) and paragraph (b)(1), revising the headings of paragraphs (a)(2) and (b)(2) and by removing the paragraph heading and adding in its place new introductory text in paragraph (c), effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) *Exception for equipment and supplies furnished prior to January 1, 2011.* * * *

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(b) * * *

(2) *Exception for home support services furnished prior to January 1, 2011.* * * *

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(c) Payment limits for support services, equipment and supplies, and notification of changes to the payment limits apply prior to January 1, 2011 as follows:

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§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.

(a) Payment for EPO used at home by a home dialysis patient is made only to